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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,066	12/04/2001	Tasuku Honjo	Q67573	3829

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,066

Applicant(s)

HONJO ET AL.

Examiner

Janet L. Andres

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-- **Th MAILING DATE of this c mmunication appears on the cover sheet with the correspond nc address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 01,5,11/03. 6) ☐ Other:

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 17 November 2003 is acknowledged. Claims 1, 2, and 10 are pending and under examination in this application.

Priority

2. With respect to the denial of priority, Applicant argues that, since the claimed invention has utility as an anti-inflammatory agent, priority should be granted to the prior applications, which also disclose this utility. However, for the reasons set forth below, Applicant's arguments with respect to the rejection of the claims under 35 U.S.C. 101 and 112 are not found to be persuasive. Thus the applications to which priority is claimed fail to provide a utility and thus are not enabling under 35 U.S.C. 112.

Information Disclosure Statement

3. Applicant has requested the return of an acknowledged copy of the form 1449 filed 4 December 2001. The references filed 4 December 2001 as well as those filed 29 May 2003 and 6 November 2003 have been considered in full and signed copies of the forms 1449 are attached.

Claim Rejections/Objections Withdrawn

4. The objection to claim 10 as depending from a non-elected claim is withdrawn in response to Applicant's amendment changing the dependency.

5. The objection to claims 1 and 2 as containing a typographical error is withdrawn in response to Applicant's amendment correcting the errors.

6. The rejection of claims 1 and 10 under 35 U.S.C. 112, second paragraph, as indefinite in the recitation of homologues is withdrawn in response to Applicant's amendment limiting the claims to polypeptides of at least 90% homology to the disclosed sequence.

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Claim Rejections Maintained

7. The rejection of claims 1, 2, and 10 under 35 U.S.C. 101 as lacking utility is maintained for reasons of record in the office action of 6 May 2003.

Applicant argues that anti-inflammatory effects are disclosed in the application on p. 15, lines 18-20. Applicant argues that subsequent teachings in the art show that the claimed polypeptide does have this function, citing Visintin et al., Akashi et al., Viriyakosol et al., and Schromm et al. Applicant concludes that the claimed invention could be used as an anti-inflammatory agent.

Applicant's arguments have been fully considered but have not been found to be persuasive. While the specification teaches a possible anti-inflammatory role for the protein, it also teaches many other potential functions on pp. 14-24, none of which is supported by objective evidence. These functions include activation and inhibition of cell proliferation and differentiation (pp. 14 and 22), immune stimulation or immune suppression (p. 14), treatment of disease in which increased immune function would be desirable (p. 15 and 16), treatment of disease in which immunosuppression would be desirable (p. 15), repair of various tissues (pp. 17-19), effects on fertility, both positive and negative (p. 19-20), chemotactic effects (p. 20), enhancement or inhibition of coagulation (p. 21), and promotion or inhibition of organogenesis (pp. 23 and 24). Thus Applicant teaches many unrelated and contradictory effects which the compound might possibly have, as was stated on p. 3 of the office action of 6 May 2003. An anti-inflammatory action is merely one of the many possibilities listed. No particular function is assigned to the claimed protein and Applicant thus does not disclose any specific and substantial

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utility, including the anti-inflammatory activity identified by subsequent research. See *In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals,

‘We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.’

See also *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), where the court held that: a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.

8. The rejection of claims 1, 2, and 10 under 35 U.S.C. 112, first paragraph, as lacking enablement because no utility has been disclosed, is maintained for reasons of record in the office action of 6 May 2003.

Applicant argues that the claims are fully enabled, since the skilled artisan would readily understand how to make and use the invention as an anti-inflammatory agent.

Since Applicant’s arguments with respect to the rejection under 35 U.S.C. 101 have not been found to be persuasive, the rejection of the claims under 35 U.S.C. 112, first paragraph, as lacking enablement is also maintained. No specific and substantial utility for the protein is set forth in the specification, for the reasons set forth in paragraph 7 above, and thus the skilled artisan would not, provided with Applicant’s disclosure, know how to use the protein.

9. The rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as lacking enablement for variants is maintained for reasons of record in the office action of 6 May 2003.

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Applicant has amended the claims to require anti-inflammatory activity and to encompass only homologues of at least 90% identity. Applicant argues that the claims are thus fully enabled.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, Applicant's specification does not disclose a specific and substantial utility for the invention. The specification does not teach one of skill in the art how to make and use variants having the same activity as the parent molecule because, for the reasons set forth above, it does not disclose any particular activity of the parent molecule. The inclusion of a functional limitation taught by the subsequent art does not serve to enable the invention since it was not enabled at the time of filing.

10. The rejection of claims 1 and 10 under 35 U.S.C. 112, first paragraph, as lacking written description of variants is maintained for reasons of record in the office action of 6 May 2003.

Applicant argues that the claims as amended require the same activity and similar structure.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, Applicant was not in possession of the anti-inflammatory activity at the time of filing; it was disclosed by the subsequent art. Thus, as stated on p. 6 of the previous office action, the disclosure fails to describe the common attributes or characteristics that identify member of the genus of homologues of SEQ ID NO: 7.

11. The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as lacking enablement for pharmaceutical compositions is maintained for reasons of record in the office action of 6 May 2003.

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Applicant argues that a utility and activity for the protein as anti-inflammatory agent has been established and that diseases that could be treated, such as SIRS and septic shock, are disclosed. Applicant further argues that use of the protein as a medicament is described on pp. 25-27.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in paragraphs 7-10 above, the specification does not disclose any particular activity for the protein or any particular disease for which it is known to be useful. What is disclosed is a list of possibilities, one of which was subsequently identified by others as an actual function. In addition, what is described on pp.25-27 are formulations, not diseases that could be treated. Thus the specification fails to disclose any particular disease that the protein could be used to treat, and, without further guidance, it would require undue experimentation for the skilled artisan to use the protein as a therapeutic agent.

12. The rejection of claims 1, 2, and 10 under 35 U.S.C. 102(b) as being anticipated by Shimazu et al. is maintained for reasons of record in the office action of 6 May 2003.

Applicant argues that a utility has been established and that this asserted utility is disclosed in the earliest priority document, as well as in the international application, and thus the Shimazu document is not prior art.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in paragraphs 7-11 above, Applicant's arguments with respect to utility have not been found to be persuasive; the specification fails to disclose a specific and substantial utility for the claimed protein. The priority documents similarly fail to disclose a utility and thus are not enabling under 35 U.S.C. 112. Priority is therefore not granted to those documents and

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the filing date of the instant application, December 2001, is the priority date granted. The Shimazu document was published in 1999 and is thus prior art under 35 U.S.C 102(b).

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (571) 272-0867. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871. The fax phone number for this group is (703) 872-9306. Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
February 2, 2004


JANET ANDRES
PATENT EXAMINER